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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Number 2003D–0558]

Draft Compliance Policy Guide, Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability; and Draft Supporting Document, Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled "Guidance Levels for Radionuclides in Domestic and Imported Foods." The draft CPG would rescind and replace the current CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14). The draft CPG provides updated guidance levels for radionuclide activity concentration in food offered for import and makes these same guidance levels for radionuclide activity concentration applicable to food in domestic interstate commerce for the first time. The draft CPG also expands the scope of coverage of FDA policy from food accidentally contaminated with radionuclides to food accidentally or intentionally contaminated with radionuclides. The agency is also announcing the availability of a draft supporting document entitled "Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods."

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DATES: Submit written or electronic comments concerning the draft CPG and/or the draft supporting document by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the draft CPG entitled "Guidance Levels for Radionuclides in Domestic and Imported Foods" and/or the draft supporting document entitled "Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods" to Paul South (see **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document. Submit written comments on the draft CPG and/or draft supporting document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640, fax: 301–436–2651, e-mail: *psouth@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed a draft CPG to rescind and replace CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14) concerning radionuclides in food. While CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14), which was issued in 1986 following the Chernobyl nuclear accident, only addresses radionuclides in food offered for import, this draft CPG is intended to provide clear policy and

regulatory guidance to FDA's field and headquarters staff with regard to radionuclides in both food offered for import and domestic food in interstate commerce. In particular, the draft CPG sets forth new guidance levels for radionuclides, referred to as Derived Intervention Levels (DILs). FDA would use DILs to help determine whether food in interstate commerce or food offered for import into the United States presents a safety concern. The DILs adopted in the draft CPG are not binding on FDA, the regulated industry, or the courts. In any given case, FDA may decide to initiate an enforcement action against food with concentrations below the DILs or decide not to initiate an enforcement action against food with concentrations that meet or exceed the DILs. The scientific basis for the DILs established in the draft CPG is presented in the draft supporting document. The draft CPG also contains information that may be useful to the regulated industry and to the public.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR § 10.115). The draft CPG is being issued as a Level 1 draft guidance consistent with GGPs. The draft CPG represents the agency's current thinking on its enforcement process concerning the adulteration of foods with radionuclides. It does not create or confer any rights for or on any person and does not operate to bind FDA, or the public.

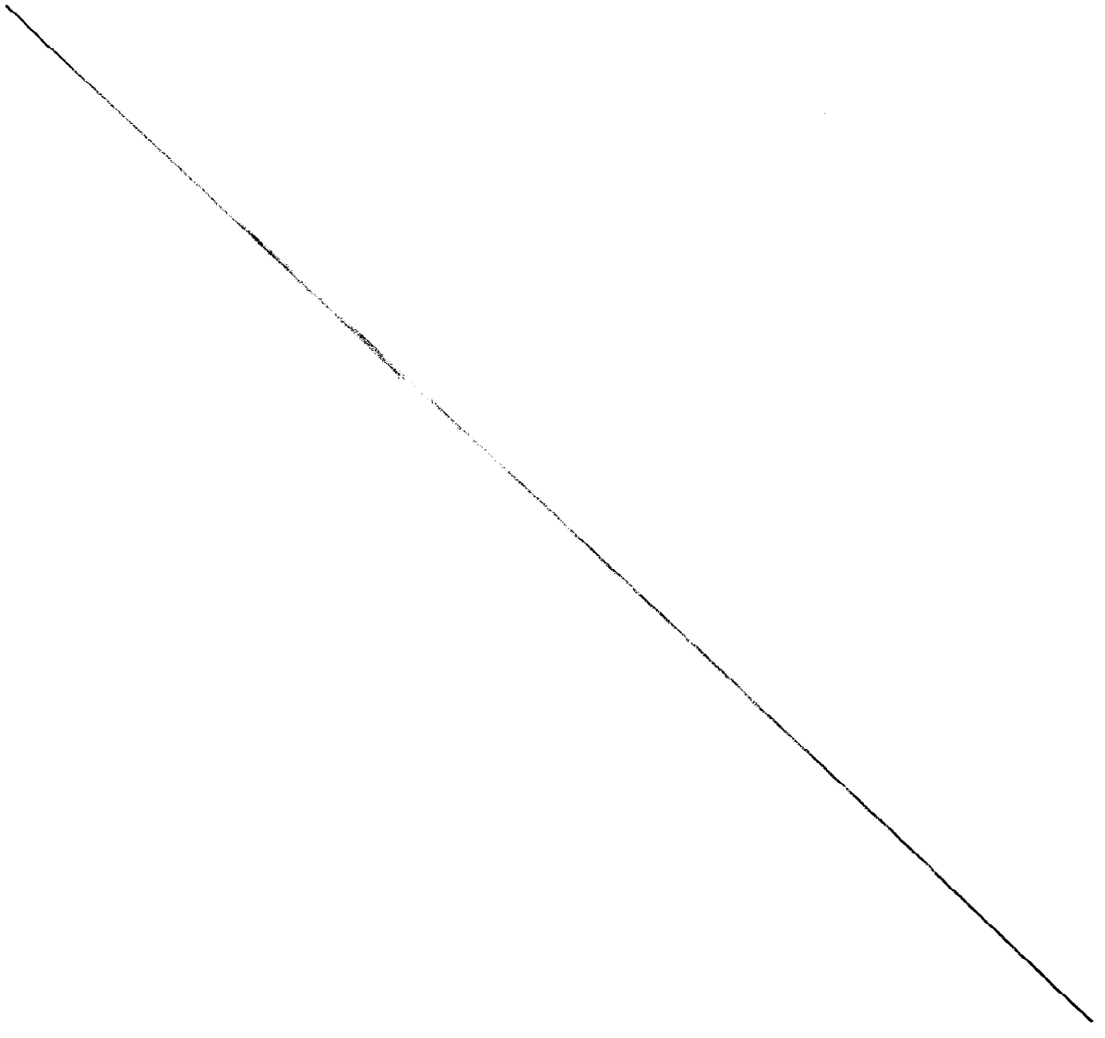
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft CPG and the draft supporting document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found

in brackets in the heading of this document. Received comments, the draft CPG, and the draft supporting document may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG and the draft supporting document at *http://www.fda.gov/ora* under "Compliance References."



Dated: January 7, 2004.

John M. Taylor,
Associate Commissioner for Regulatory Affairs.

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